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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,334	06/22/2000	Thomas Graf	2565/74	7641

26646 7590 07/15/2003

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

[REDACTED] EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/599,334	GRAF ET AL.
	Examiner Patricia M Bianco	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 18 March 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-7 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 7 and 9-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1.) Certified copies of the priority documents have been received.  
 2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b)  
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7, 12, and 13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bene (5,744,031). Bene discloses a dialysis system comprising a dialyzer (1) divided by a semipermeable membrane (4) into a blood chamber (2) and a dialysis chamber (3). The blood chamber has an inlet connected to an arterial blood line (5) and an outlet connected to a venous blood line (7). Since the claim is open-

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ended (i.e. "comprising"), the venous line is seen to be connected to the blood outlet regardless of the intervening bubble trap. Further, the claim does not require that the venous line be "directly connected" to the outlet. Therefore this limitation is met. The dialysis chamber has an inlet connected to a dialysis fluid inlet line (13) and an outlet connected to a dialysis fluid outlet line (29). A blood pump (6) is connected to the arterial, a first dialysis fluid pump (15) is connected to the dialysis inlet line and a second dialysis fluid pump (22) is connected to the dialysis fluid outlet line. Bene also discloses flow meters (24/25) measure the inflow and outflow rates of the dialysis fluid. Bene also discloses that the computing and control unit (26) can calculate the dialysance of the apparatus during the treatment session based on blood flow rate and/or dialysis liquid flow rate values sent to the control unit (see figure 1 & col. 4, line 33-col. 6, line 51). With respect to claim 7, since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it is the position of the examiner that the computing and control unit of Bene is equivalent to that of a computer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bene ('031). Bene discloses the invention substantially as claimed, see rejection supra. Bene, however, fails to disclose specifically that the computer calculates a diffusive component D1, effective blood flow Qe (claim 9), the diffusive dialysance  $D(Qd(t))$  for any flow rate  $Qd(t)$  (claim 10), and the sum of the diffusive and convective dialysance  $k(Qd(t), Qe, Of(t))$  or the clearance from the diffusive dialysance  $D(Qd(t), Qe(t))$  according to their respective equations set forth in their respective claims. However, since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it clearly uses programmable software to perform the mathematical calculations. Therefore, the computing and control unit of Bene is clearly capable of being programmed with the required equations such that the control unit can calculate the diffusive component D1, effective blood flow Qe (claim 9), the diffusive dialysance  $D(Qd(t))$  for any flow rate  $Qd(t)$  (claim 10), and the sum of the diffusive and

convective dialysance  $k(Qd(t), Qe, Of(t))$  or the clearance from the diffusive dialysance  $D(Qd(t),Qe(t))$ . It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computing and control unit of Bene to store the desired equations to calculate diffusive component D1, effective blood flow Qe (claim 9), the diffusive dialysance  $D(Qd(t))$  for any flow rate  $Qd(t)$  (claim 10), and the sum of the diffusive and convective dialysance  $k(Qd(t), Qe, Of(t))$  or the clearance from the diffusive dialysance  $D(Qd(t),Qe(t))$ , since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 3/18/03 have been fully considered but they are not persuasive. Applicant argues that Bene does not teach of a means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and dialysance at the at least one of a blood flow rate, a dialysis fluid flow rate, and an ultrafiltration rate, on the basis of the at least one of a predetermined blood flow rate, predetermined dialysis fluid flow rate, and a predetermined ultrafiltration rate. The examiner respectfully disagrees. Bene teaches that the computing and control unit 26 controls the system based on signals measured throughout the entire system according to parameters that it calculates, such as blood flow rate, and parameters of the performance of the system, such as dialysance, and according to the data that is supplied to the computing or control unit 26 prior to the start

of treatment, such as a desired blood flow rate of the blood or the dialysis fluid (col. 5, line 65-col. 6, line 25). The data supplied to the computing or control unit 26 prior to the start of treatment is equal to the "predetermined" rates of applicant's argument. Further, Bene also states that the computing or control unit 26 calculates by extrapolation on the basis of the dialysance, and according to known rules of correspondence, the clearance of the urea, depending on both the characteristics of the exchanger and the flow rates of the blood and of the dialysis liquid. The calculated clearance is compared by the computing or control unit 26 with the desired clearance. The desired clearance is stored in the unit at time of programming. If required, the computing or control unit 26 will modify the programmed treatment session based on its calculations (col. 7, lines 11-35). Since the computing or control unit 26 of Bene independently calculates values based upon comparisons of measured parameters of the system with data programmed into the unit at the beginning of treatment, it is seen to be a computer. Therefore, it is the position of the examiner that the computing or control unit 26 of Bene is disclosed a computer unit that can determine clearance or dialysance based upon at least one of the clearance and dialysance and at least one of a blood flow rate and dialysis fluid flow rate, with at least one of a predetermined blood flow rate, predetermined dialysis fluid flow rate, and a predetermined ultrafiltration rate.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb *T. Bianco*  
July 11<sup>th</sup>, 2003